

Attorney's Docket 037003-0307368

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re PATENT APPLICATION of:
NABIL HANNA ET AL.

Confirmation No: 9111

Application No.: 10/743,739

Group Art Unit: 1642

Filed: December 24, 2003

Examiner: Gary B. Nickol

Title: SYNERGISTIC COMPOSITION AND METHODS FOR TREATING
NEOPLASTIC OR CANCEROUS GROWTHS AND FOR RESTORING OR BOOSTING
HEMATOPOIESIS

DEC 12 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450CERTIFICATION OF FACSIMILE TRANSMISSION
UNDER 37 C.F.R. §1.8

I hereby certify that the following papers, consisting of five sheets including this cover sheet, are being facsimile transmitted to the Patent and Trademark Office at (571) 273-8300 on the date shown below:

Supplemental Information Disclosure Statement

PILLSBURY WINTHROP SHAW PITTMAN LLP

THOMAS A. CAWLEY, JR., PH.D.
Reg. No. 40944

Date: December 12, 2005
P.O. Box 10500
McLean, VA 22102
Telephone: (703) 770-7900
Facsimile: (703) 770-7901

(Certification of Facsimile Transmission--page 1)

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For: SYNERGISTIC COMPOSITION AND METHODS FOR TREATING NEOPLASTIC OR
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

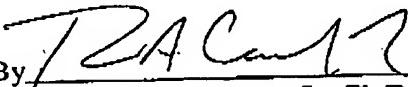
Commissioner for Patents
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Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56, 1.97, and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. Applicants respectfully request the examiner return an initialed copy of the enclosed Form PTO-1449 to applicants with the next Office communication to indicate that the references have been considered, per M.P.E.P. § 609.

The references were cited by the applicant or examiner during the prosecution of U.S. Patent Application No. 09/853,581, filed May 14, 2001, and/or U.S. Patent Application No. 08/933,359, filed on September 18, 1997, to which the present application claims priority pursuant to 35 U.S.C. § 120. Thus, copies of the references listed in the attached PTO-1449 are not attached. This Information Disclosure Statement is being filed before the mailing of a first office action on the merits in the present application. No certification or fee is required.

Respectfully submitted,

By 
 Thomas A. Cawley, Jr., Ph.D.
 Reg. No. 40944
 Tel. No. 703.770.7944
 Fax No. 703.770.7901

Date: December 12, 2005

PILLSBURY WINTHROP SHAW PITTMAN LLP
 P.O. Box 10500
 McLean, VA 22102
 703.770.7900

FORM PTO-1449 (modified)
 To: U.S. Department of Commerce
 (PW FORM PAT-1449)
 Patent and Trademark Office

Atty. Dkt. No.: 037003-0307368

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Applicant: NABIL HANNA et al.

U.S. Patent Application. No.: 10/743,739

Filing Date: December 24, 2003

Examiner: Gary B. Nickol Group Art Unit: 1642

Date: December 12, 2005 Page 1 of 3

U.S. PATENT DOCUMENTS

Examiner's Initials*	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
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BR	5,514,670	05/1996	Friedman et al.	514	2	08/1993
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DR	5,932,212	09/1999	Khalaif (first page and the page with column 10 only).	---	---	
ER	6,197,311	03/2001	Raychaudhuri et al. (claims only)	---	---	

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					Yes	No	Enclosed
FR	WO 9409815 A1	05/1994	WIPO	Segarini et al.			
GR							

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

HR	Berd et al. "Induction of cell-mediated immunity to autologous melanoma cells and regression of metastases after treatment with a melanoma cell vaccine preceded by cyclophosphamide," <i>Cancer Research</i> , 1986, 46(5):2572-2577.
IR	Blondino et al., "The quantitative determination of aspirin and its degradation products in a model solution aerosol," <i>J Pharm Biomed Anal.</i> , 1995, 13(2):111-9 (abstract only).
JR	Brown et al., "Either interleukin-12 or interferon-gamma can correct the dendritic cell defect induced by transforming growth factor beta in patients with myeloma," <i>Br J Haematol.</i> 2004 Jun;125(6):743-8.
KR	Carbone et al., "Class I-Restricted Processing and Presentation of Exogenous Cell-Associated with Antigen In Vivo," February 1990, 171:377-387.
LR	Clarke et al., "Lisofylline inhibits transforming growth factor beta release and enhances trilineage hematopoietic recovery after 5-fluorouracil treatment in mice," <i>Cancer Research</i> , 1996, 56(1):105-112.
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QR	Hasegawa et al., "Transforming growth factor-beta1 level correlates with angiogenesis, tumor progression, and prognosis in patients with nonsmall cell lung carcinoma." <i>Cancer</i> . 2001 Mar 1;91(5):964-71.
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SR	Jacobsen et al., "Transforming growth factor-beta potently inhibits the viability-promoting activity of stem cell factor and other cytokines and induces apoptosis of primitive murine hematopoietic progenitor cells," <i>Blood</i> 1995, 86(8):2957-2966.
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		U.S. Patent Application. No.: 10/743,739
		Filing Date: December 24, 2003
Date: December 12, 2005 Page 2 of 3		Examiner: Gary B. Nickol Group Art Unit: 1642

UR	Lee et al., "Aberrant expression of Smad4 results in resistance against the growth-inhibitory effect of transforming growth factor-beta in the SiHa human cervical carcinoma cell line," <i>Int J Cancer</i> . 2001 Nov 15;94(4):500-7.
VR	Lian et al., "Enhanced expression of transforming growth factor-beta isoforms in the neural tube of embryos derived from diabetic mice exposed to cyclophosphamide," <i>Neurosci Lett</i> . 2003 Nov 6;351(1):51-5.
WR	Matar et al., "Mechanism of antimetastatic immunopotentiation by low-dose cyclophosphamide," <i>Eur. J. Cancer</i> , May 2000, 36(8):1060-1066.
XR	Matar et al., "Down regulation of T-cell-derived IL-10 production by low-dose cyclophosphamide treatment in tumor-bearing rats restores in vitro normal lymphoproliferative response," <i>Int Immunopharmacol</i> . 2001 Feb;1(2):307-19.
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FFR	Piestrzeniewicz-Ulanska et al., "Expression and intracellular localization of Smad proteins in human endometrial cancer," <i>Oncol Rep</i> . 2003 Sep-Oct;10(5):1539-44.
GGR	Sacco et al., "Transforming growth factor beta1 and soluble Fas serum levels in hepatocellular carcinoma," <i>Cytokine</i> . 2000 Jun;12(6):811-4.
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JJR	Schmolka, "A Review of Block Copolymer Surfactants," <i>J. Am. Oil. Chem. Soc.</i> , 1977, 54(3):110-116.
KKR	Seoane et al., "Integration of Smad and forkhead pathways in the control of neuroepithelial and glioblastoma cell proliferation," <i>Cell</i> . 2004 Apr 16;117(2):211-23.
LLR	Shariat et al., "Preoperative plasma levels of transforming growth factor beta(1) (TGF-beta(1)) strongly predict progression in patients undergoing radical prostatectomy," <i>J Clin Oncol</i> . 2001 Jun 1;19(11):2856-64.
MMR	Shariat et al., "Preoperative plasma levels of transforming growth factor beta(1) strongly predict clinical outcome in patients with bladder carcinoma," <i>Cancer</i> . 2001 Dec 15;92(12):2985-92.
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OOR	Sitnicka et al., "Transforming growth factor beta 1 directly and reversibly inhibits the initial cell divisions of long-term repopulating hematopoietic stem cells," <i>Blood</i> , 1996, 88(1):82-88.

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		Examiner: Gary B. Nickol Group Art Unit: 1642
Date: December 12, 2005 Page 3 of 3		

PPR	Subramanian et al., "Targeting endogenous transforming growth factor beta receptor signaling in SMAD4-deficient human pancreatic carcinoma cells inhibits their invasive phenotype1," <i>Cancer Res.</i> 2004 Aug 1;64(15):5200-11.
QQR	Takahashi et al., "Induction of CD8 ⁺ Cytotoxic T Cells by Immunization with Purified HIV-1 Envelope Protein in ISCOMs," <i>Nature</i> , April 26, 1990, 344:873-875.
RRR	Takiguchi et al., "Profile of cytokines produced in tumor tissue after administration of cyclophosphamide in a combination therapy with tumor necrosis factor," <i>Anticancer Res.</i> 2004, 24(3a):1823-8.
SSR	Weiner et al., "Treatment of multiple sclerosis with cyclophosphamide: critical review of clinical and immunologic effects," <i>Mult Scler.</i> 2002 Apr;8(2):142-54.
TTR	Xi et al., "Dysregulation of the TGF-beta postreceptor signaling pathway in cell lines derived from primary or metastatic ovarian cancer," <i>J Huazhong Univ Sci Technolog Med Sci.</i> 2004;24(1):62-5.
UUR	Xiong et al., "Transforming growth factor-beta1 in invasion and metastasis in colorectal cancer. <i>World J Gastroenterol.</i> " 2002 Aug;8(4):674-8.
VVR	Xu et al., "Elevated serum levels of transforming growth factor beta1 in Epstein-Barr virus-associated nasopharyngeal carcinoma patients." <i>Int J Cancer.</i> 1999 Aug 20;84(4):396-9.

Examiner	Date Considered:
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	